

DEPARTMENT OF HEALTH AND HUMAN SERVICES

**Substance Abuse and Mental Health Services Administration
Center for Substance Abuse Treatment**

**Guidance for Applicants (GFA) No. TI 02 - 004
Part I - Programmatic Guidance**

**Cooperative Agreements
for
State Treatment Needs Assessment Program**

Short Title: STNAP

Application Due Date:
July 24, 2002

H. Westley Clark, M.D., J.D., M.P.H., CAS, FASAM
Director, Center for Substance Abuse Treatment
Substance Abuse and Mental Health
Services Administration

Charles G. Curie, M.A., A.C.S.W.
Administrator
Substance Abuse and Mental Health
Services Administration

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[Note to Applicants: To prepare a complete application, PART II - "General Policies and Procedures Applicable to all SAMHSA Applications for Discretionary Grants and Cooperative Agreements" (February 1999), must be used in conjunction with this document, PART I - "Programmatic Guidance."]

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Agency

Department of Health and Human Services,
Substance Abuse and Mental Health Services
Administration

Action and Purpose

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT) announces the availability of FY 2002 funds for cooperative agreements to implement the State Treatment Needs Assessment Program (STNAP). The STNAP provides assistance to States for conducting evaluations of their substance abuse treatment services needs to determine ways to improve the availability and quality of treatment services.

Approximately \$3.0 million will be available for 10 to 12 awards. Annual awards may not exceed \$300,000, in total costs (direct and indirect). Actual funding levels will depend on the availability of funds.

Awards may be requested for up to three years. Annual continuation awards are subject to continued availability of funds and progress achieved.

This is a reissuance of the CSAT FY 2001 STNAP GFA No. TI 01- 010.

Background

The STNAP was established to assist States in fulfilling their statutory responsibilities found under Section 1929 of the Public Health Service

(PHS) Act for submitting an assessment of their treatment services needs in order to receive an award under the Substance Abuse Prevention and Treatment Block Grant (SAPT Block Grant). The first awards, contracts, were made in 1992 to the States for conducting a family of studies for assessing their treatment services needs. Beginning in 1996, many States received a second contract award which resulted in the enhancement of previously collected data and an opportunity for support to conduct more specialized analyses. Because of the need to address changes in substance abuse services, limited availability of funds, and the need at the Federal level for the availability of core data across States, as well as anticipated changes in relevant legislation, the STNAP was reconceptualized in 1999. Awards were made to six States for collecting and/or obtaining data using core protocols to enable CSAT to aggregate data across States. These the awards were made as grants to allow States the flexibility to propose projects designed to meet their specific needs for assessing their treatment services needs.

Under SAMHSA's reauthorization in October 2000, the funding authority for the STNAP was amended to require States that receive STNAP funding to continue to collect and report core data to CSAT on an annual basis after the project's end. As a result, in 2001, the program approach was adjusted to insure compliance with the new legislation. These awards were made as cooperative agreements to allow for the necessary Federal involvement and guidance throughout the project period. As a result, eight States received awards in FY 2001.

Also under the October 2000 SAMHSA reauthorization came the funding authority for the State Data Infrastructure Program (SDI). The primary goal of the SDI is to help States report performance data as required by the Performance Partnerships Grants on their annual SAPT Block Grant applications. It should be noted that basic State specific data derived from the STNAP can be used to construct data for performance measures in the areas of penetration rates, utilization patterns, and outcomes. For example, the Administrative, Client-Level Treatment Data Core Protocol provides data on the number of clients treated, and one or more of the other Core Protocols can be used to estimate the number of people that need treatment. These data are used in calculating penetration rates.

National Treatment Plan

On November 28, 2000, CSAT released "Changing the Conversation: Improving Substance Abuse Treatment: The National Treatment Plan Initiative" (NTP). The STNAP addresses NTP strategies, "Invest for Results," "No Wrong Door," and "Commit to Quality," through providing planning tools for allocating substance abuse services resources. Thus, the STNAP assists in the wise use of resources to better serve those in need. For additional information about the NTP and how to obtain a copy, see Appendix A of this document.

Who Can Apply

Applications are limited to the Single State Authorities (SSAs) because the States have statutory responsibility to develop and submit services needs assessment estimates in order to

receive a SAPT Block Grant award. The term "State(s)" includes SSAs (or equivalent to) for all 50 States, the District of Columbia, Guam, Puerto Rico, the Northern Mariana Islands, the Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands.

States may have only one active STNAP award (grant/cooperative agreement/contract) at any given time. However, an application under this GFA may be submitted during the last year of an existing award with the understanding that such an application, if approved, will not be considered for award **unless** all work on the prior award has been completed. For contracts "completed" is defined as all deliverables have been received and approved by the GPO. For grants or cooperative agreements "completed" is defined as all reporting and data submission requirements have been met and approved by the GPO.

Application Kit

SAMHSA application kits, also called Guidance for Applicants or GFA, include a two-part announcement and the blank forms needed for preparing the application.

The STNAP Cooperative Agreement Application Kit includes:

- c Part I Programmatic Guidance -** Provides guidance specific to the STNAP cooperative agreement. This document is Part I.
- c Part II General Policies and Procedures -** Provides important

policies and procedures that apply to nearly all SAMHSA applications for grants and cooperative agreements. Please refer to the section entitled Special Considerations and Requirements in this document for a listing of policies in Part II that are relevant to this program.

- c FORM PHS-5161-1 (Revised 7/00)** - Includes required blank forms for preparing the application.

You must use Part I and Part II of the GFA, and FORM PHS 5161-1 to apply.

Other materials included are:

- c Protection of Human Subjects Assurance Identification/ Certification/Declaration (Optional Form 310 (Rev. 1/98))** - Projects proposed under this GFA are subject to the requirements of Title 45 of the Code of Federal Regulations, Part 46 (45 CFR 46). Follow the directions on the form and return a completed form with the application.
- c OMB State Single Point of Contact Listing** - See Part II of the GFA in the section entitled "Intergovernmental Review (E.O. 12372)" for instructions and more information.
- c Assurance of Compliance** - Title VI of the Civil Rights Act of 1964, (Form HHS-690) - See FORM PHS 5161-1, Part A of the "Checklist." The Form HHS-690 is included for use by the

those States who may need to file the relevant assurances with DHHS. Instructions are included on the form.

Complete application kits for STNAP cooperative agreements will be mailed directly from SAMHSA/CSAT by the Government Project Officer (GPO) to the SSAs for the States. For additional copies please contact:

Nita Fleagle, GPO
Center for Substance Abuse Treatment
SAMHSA
Rockwall II, Suite 840
5600 Fishers Lane
Rockville, MD 20857
Phone: (301) 443-8572
E-Mail: nfleagle@samhsa.gov

Where to Send the Application

Send the original and 2 copies of the application to:

SAMHSA Programs
Center for Scientific Review
National Institutes of Health
Suite 1040
6701 Rockledge Drive MSC-7710
Bethesda, MD 20892-7710

Note:

- c** Change the zip code to 20817 if express mail or courier service is used. If a phone number is required for delivery, 301-435-0715 may be used.

- c Effective immediately, all applications must be sent via a recognized commercial or government carrier. Hand-carried applications will not be accepted.
- c Please be sure to type TI 02-004 STNAP in block 10 of the face page of the application (Standard Form 424 of FORM PHS 5161-1).

Application Dates

The application must be received by July 24, 2002.

Applications received after July 24, 2002, must have a proof-of-mailing date from the carrier not later than July 17, 2002.

Private metered postmarks **are not** acceptable as proof of timely mailing. Late applications will be returned without review.

How to Get Help

For questions on *program issues*, contact:

Nita Fleagle, GPO
Center for Substance Abuse Treatment
SAMHSA
Rockwall II, Suite 840
5600 Fishers Lane
Rockville, MD 20857
Phone: (301) 443-8572
E-Mail: nfleagle@samhsa.gov

For questions on *grants management issues*, contact:

Stephen Hudak

Division of Grants Management, OPS
SAMHSA
Rockwall II, 6th floor
5600 Fishers Lane
Rockville, MD 20857
Phone: (301) 443-9666
E-Mail: shudak@samhsa.gov

Award Criteria

Decisions for making STNAP cooperative agreement awards are based on:

- c Strengths and weaknesses of the application as shown by a peer review committee and approved by the CSAT National Advisory Council.
- c Availability of funds

Cooperative Agreement

Awards will be made as cooperative agreements because of the complexity of the program and the anticipation of ongoing involvement of Federal staff in annual reporting of core data. The STNAP cooperative agreement between the State and CSAT will include the following terms.

States Will:

- c cooperate fully with CSAT staff and CSAT's representative contractor(s);
- c comply with all aspects of the program requirements and terms and conditions of award; and

- c accept guidance and respond to requests for information and data relevant to the program.

CSAT Staff Will:

- c provide specialized guidance on project design, including data collection activities and analyses, and core protocols throughout the course of the project;
- c obtain the necessary OMB clearance for primary data collection surveys;
- c review and approve any programmatic changes to the project post award; such as: change in objectives, change in project design, and adjustments or revisions to core protocols and instruments;
- c participate on committees/meetings or in other functions responsible for helping to guide the course of the project; and
- c conduct site visits, subject to the availability of funds, to closely monitor the development and implementation of programmatic activities.

Performance Monitoring

The Government Performance and Results Act (GPRA) requires the Federal government to assess the results of each of its activities. In the case of the STNAP, the ultimate measure of success is the ability of the States to provide valid, reliable data relating to needs for treatment services on their annual SAPT Block Grant application. Data for reporting on performance

will be developed based on reviews of the completeness and accuracy of the States services needs data submitted on the SAPT Block Grant application and does not require any specific activity by the State.

In terms of overall program evaluation, the routine progress and final reports will be reviewed against the project time lines in the application. The core data submitted after the project ends will be reviewed for adherence to the appropriate core protocol as well as checked for reliability and validity to the extent possible. This information will be used to assess the success of individual States in accomplishing the STNAP objectives.

Program Overview

The STNAP Objectives are:

- c to assist States to develop estimates of need for treatment service (both by Statewide and sub-State) required on their annual SAPT Block Grant applications;
- c to assist States in improving and institutionalizing their capability to manage data collection and analyses relating to treatment services needs;
- c to assist States to supplement existing treatment services data for a better understanding of their services needs for planning and resource allocation to improve the availability and quality of treatment services within the State; and

- c to allow for aggregation of data across States for SAMHSA/CSAT to use in secondary analyses and for augmenting other information collected within SAMHSA.

States are expected to accomplish the STNAP objectives through the use of core protocols. The use of core protocols for all data collection activities will maximize CSAT's ability to aggregate data across States for use in secondary analyses and augmentation of other information collected within SAMHSA. The core protocols offered under the STNAP include basic design, data collection methods and core data elements. States may propose additions relevant to the core protocols to generate State specific information. Examples of additions to core protocols are included in Appendix B of this document.

All States receiving an award under this program are legislatively required to continue to collect and report core data to CSAT on an annual basis after the project's end. States must use the Administrative, Client-Level Treatment Data Core Protocol for meeting this requirement. Administrative client-level treatment data are useful to the State and CSAT for multiple purposes. For example:

- c States can meaningfully disaggregate these data for reporting sub-State estimates required in the SAPT Block Grant application.
- c States can capture information about illicit drugs and drug users not found in general population surveys.

- c CSAT can aggregate these data across States for further analysis.

The Core Protocols are:

Required -

The **Administrative, Client-Level Treatment Data Core Protocol** is required under the STNAP cooperative agreement.

Optional -

States may (or may not) choose to use one or more of the following core protocols:

- **STNAP Survey** - primary data collection intended to be used for general household populations or special populations

- **Criminal Justice** - primary data collection for arrestee and inmate populations

- **Database Linkages** - secondary data analysis

- **Social Indicators** - secondary data analysis

Note: Descriptions of core protocols are included in Appendix B of this document. For copies of core protocols, call Nita Fleagle, GPO, on (301) 443-8572 or e-mail at nfleagle@samhsa.gov.

OMB clearance is required for the primary data collection activities conducted through the

STNAP Survey and the Criminal Justice Core Protocols. Data collection under these core protocols may not be implemented until CSAT obtains OMB clearance.

CSAT encourages States to make use of any of the following sources for assistance in making proposal decisions for their STNAP application.

- National Household Survey on Drug Abuse (NHSDA)
- Treatment Episode Data Set (TEDS)
- Drug Abuse Warning Network (DAWN)
- Drug and Alcohol Services Information System (DASIS)

Post Award and Reporting Requirements

Annual Meetings:

- c A minimum of two STNAP project representatives are expected to attend each STNAP Annual Meeting.
- c The meeting(s) will be held in the Washington, D.C., area for approximately 2 days and should be budgeted for in the application.

Reporting Requirements:

- c **Progress Reports** - States will be required to submit semi-annual progress reports. The following will be reported:

- status of each activity funded;
- difficulties or problems encountered;
- necessary changes or adjustments; and
- items of special interest or relevance.

- c **Final Reports** - States will be required to submit a final report at the end of the project period that includes:

- overall project accomplishments;
- discussion of how the STNAP objectives were met; and
- summary of activity findings and their usefulness.

Further guidance for all reports will be provided post award by the GPO.

Submission of Data:

- c States will be required to submit to CSAT a fully documented copy of all core data collected at the end of the project period. Data collected through the **Administrative, Client-Level Treatment Data Core Protocol**, will be reported to CSAT annually. Specifications for data submission include:

- an electronic version of the cleaned and edited final data set, in a standard

format (SPSS, SAS, DBF or similar);
and

- a hard copy and electronic version of
the data dictionary and codebook, and
any other appropriate documentation as
described in the core protocols (Word,
WordPerfect or compatible).

Preparing the Application - What to Include

In order for the application to be **complete**, it
must include the following in the order listed.
For your convenience, boxes are provided for
checking off areas as you complete them for
your application.

' 1. FACE PAGE

Use the Standard Form 424 found in the FORM
PHS 5161-1. See Appendix A in Part II of the
GFA for instructions. In signing the face page of
the application, you are agreeing that the
information is accurate and complete. Be sure
to type **TI 02-004 STNAP** in block 10.

' 2. ABSTRACT

Your total abstract may **not** be longer than 35
lines. In the **first 5 lines or less** of your
abstract, write a summary of your project that
can be used in publications, reporting to
Congress, or press releases, if your project is
awarded.

' 3. TABLE OF CONTENTS

Include page numbers for each of the major
sections of your application **and** for each
appendix.

' 4. BUDGET FORM

Fill out sections B, C, and E of the Standard
Form 424A found in the FORM PHS 5161-1.
See Appendix B in Part II of the GFA for
instructions.

' 5. PROJECT NARRATIVE/REVIEW CRITERIA AND SUPPORTING DOCUMENTATION

The **Project Narrative/Review Criteria** for
your application include sections A through D
as listed below. Detailed guidance for what to
include is found under the **Project
Narrative/Review Criteria - Sections A
Through D Highlighted**, following number 9
of this checklist.

' Section A - *Understanding the issues and need*

' Section B - *Project plan*

' Section C - *Data collection and analysis*

' Section D - *Project management plan, staff, equipment, facilities, and resources.*

The **Supporting Documentation** for your
application must be provided in Sections E
through H as listed below. There are no page

limits for Sections E, F, and H. However, there are page limitations for biographical sketches and job descriptions as specified in Section G.

‘ **Section E - *Literature citations***

This section must contain complete citations, including titles and all authors, for any literature you cite in your application.

‘ **Section F - *Budget justification, existing resources, other support***

Provide a narrative budget justification for direct costs requested which describes how the categorical costs are derived. Discuss the necessity, rationale and allocation of the proposed costs. Be sure to include the level of effort for all staff. Provide a detailed budget for each budget period. Use the formats and guidance included in Part II of the GFA, Appendix B, Example A for developing this section of your application.

‘ **Section G - *Biographical sketches and job descriptions***

Ⓒ Include a biographical sketch for the project director and for other key positions. Each sketch should not be longer than **2 pages**. If the person has not been hired, include a letter of commitment from the individual with his/her sketch.

Ⓒ Include job descriptions for key personnel. They should not be longer than **1 page**.

Note: Sample sketches and job descriptions are outlined in Item 6 in the Program Narrative section of the FORM PHS 5161-1.

‘ **Section H - *Confidentiality and Protection of Human Subjects***

There are seven areas you need to address in this section. More detailed information on what to include in this section is found under **Confidentiality and Protection of Human Subjects - Section H Highlighted** in this document.

‘ **6. APPENDICES**

Ⓒ **Don’t** use appendices to extend or replace **Project Narrative/Review Criteria, Sections A through D**. Appendices used for this purpose will **not** be considered by the peer review committee.

Ⓒ **Use only the appendices listed below.**

Appendix 1: This appendix is to be used for “Letters of Coordination and Support” and should **not** be longer than 10 pages in total.

Appendix 2: If applicable, this appendix is to be used for “Proposed Additional Questions to the STNAP or Criminal Justice Surveys.”

Appendix 3: This appendix is to be used for a “List of Acronyms,” with definitions, used in the application

7. ASSURANCES AND CERTIFICATIONS

C Assurances - Non-Construction

Programs - Complete the “Certifications” form, Standard Form 424B, found in FORM PHS 5161-1.

C Human Subjects Certification -

Under the STNAP cooperative agreement, projects that involve human subjects are subject to the requirements of Title 45 of the Code of Federal Regulations, Part 46 (45 CFR 46) and Human Subject Certifications are applicable for those projects. See FORM PHS 5161-1 “Checklist”, Part A, number 5. Complete the Protection of Human Subjects Assurance Identification/Certification/ Declaration (Optional Form 310 (Rev.1/98)) included in the application kit. Follow the instructions on the form and include a completed form with the application. For guidance for obtaining Human Subjects Assurance see Part II of the GFA in the section entitled “Confidentiality/SAMHSA Participant and Human Subject Protection.”

8. DISCLOSURE OF LOBBYING ACTIVITIES

Use Standard Form LLL (Rev. 7-97) (and LLL-A, if needed) found in the FORM PHS 5161-1. For guidance regarding lobbying activities, please see Part II of the GFA in the section entitled “Lobbying Prohibitions.”

9. CHECKLIST

Use the “Checklist” included in the FORM PHS 5161-1. See Appendix C in Part II of the GFA for instructions.

Project Narrative/ Review Criteria – Sections A Through D Highlighted

Sections A through D are the project narrative/review criteria parts of your application and must describe what you intend to do with your project. Below you will find detailed information on how to respond to sections A through D.

C Sections A through D may not be longer than 25 pages in total. See Part II of the GFA in the section entitled “Application Instructions” for details on issues such as number of copies, assembly and other page formatting (font, margins, spacing, etc.). **Failure to comply with these specifications will result in your application not being reviewed by the peer review committee.**

C A peer review committee will assign a point value to your application based on how well you address sections A through D. For additional information see Part II of the GFA in the section entitled “Review Process.”

C The number of points after each Section heading (Sections A through D) shows the maximum points a peer

review committee may assign to that category. For example, a perfect score for Section A will result in a rating of 25 points. The bulleted statements that follow each Section heading serve as a guide to the applicant for the areas that must be addressed in that Section. The bulleted statements **do not** have weights.

- C The peer review committee will also be looking for cultural competence. Cultural competence issues to be addressed are included, as appropriate, in Sections A through D. Points will be deducted from applications that do not adequately address the cultural aspects of the criteria. See Appendix D in Part II of the GFA entitled “Guidelines for Assessing Cultural Competence.”

Section A - *Understanding the issues and need (20 points)*

- ‘ Provide information on the State’s previous STNAP activities. Include accomplishments and how you have used those findings.
- ‘ Describe how the State uses services needs information in completing SAPT Block Grant reporting and how the proposed activities will contribute to future reporting.
- ‘ Describe proposed activities and justify the need for each. Include how the proposed activities will add to existing services needs data.

- ‘ Describe how the data and information obtained through the proposed activities will be used to improve resource planning and allocation for improving the availability and quality of treatment services.

Section B - *Project plan (30 points)*

- ‘ List the purpose and objectives of the proposed project and describe how they relate to meeting the purpose and objectives of the STNAP.
- ‘ Describe any population(s) targeted by the project and explain why the population(s) was chosen.
- ‘ Describe how the proposed activities are sensitive to cultural values and needs of the target population, related to language, race/ethnicity, gender, age, sexual orientation, disability and literacy levels as well as any other factors important in understanding the population.
- ‘ Describe how the State will implement the required Administrative, Client-Level Treatment Data Core Protocol. Provide a rationale for any proposed additions to this core protocol.
- ‘ Describe how the State will obtain participation from providers for the Administrative, Client-Level Treatment Data Core Protocol.
- ‘ Include a plan for how the State will continue to report annual data collected, using the Administrative,

Client-Level Treatment Data Core Protocol, beyond the Federally-funded program years.

- ' Describe how the State will implement any other core protocol(s) proposed. Include a rationale for any proposed additions to the core protocol(s). Provide any proposed additional questions to the STNAP or Criminal Justice Surveys in Appendix 2 of the application.
- ' Describe any collaboration or commitment with other State, local, or Federal agencies. Include supporting letters or documents in Appendix 1 of your application.

**Section C - Data collection and analysis
(30 points)**

- ' Describe the relevant methodology, (sampling design where appropriate), strategies for developing valid and reliable measures, and data analyses plans to be used.
- ' Describe how findings will be interpreted in a culturally sensitive manner.
- ' If the State is proposing to use the STNAP Survey and/or Criminal Justice Core Protocols, describe how the target population will be identified recruited and retained. Include how issues and needs, and any other unique features that call for special attention for this population will be addressed.

- ' Describe plans for collecting data, including who will do data collection, and how data will be stored.

- ' Describe database management, data processing and clean-up, record matching, quality control, and data retention.
- ' Describe the level of data collection capabilities of provider(s) for the Administrative, Client-level Treatment Data Core Protocol.
- ' Describe the effects that any proposed additions to core protocols may have on the quality of the information obtained. For example, changes in response rates due to adding questions to instruments or changes in the quality of analysis from adding databases to the secondary data analysis.

**Section D - Program management plan, staff, equipment, facilities, and resources
(20 points)**

- ' Describe the qualifications and experience of the project director and other key personnel, including proposed consultants and subcontractor staff.
- ' Describe staff composition and their overall competence to address the culture, values and needs of the target population, including language, race/ethnicity, gender, age, sexual orientation, disability, and literacy levels.

- ' Describe the State's capability and experience with similar projects and populations.
- ' Describe the project management plan. Give a time line for tasks and provide a staffing plan with reasons for the amount of time allocated for key personnel and consultants.
- ' Describe the available equipment and facilities and explain how they are adequate to support the proposed project.

Note: Although the **budget** for the proposed project is not assigned points for review, the peer review committee will be asked to comment on the budget after the merits of the application have been considered.

Confidentiality and Protection of Human Subjects - Section H Highlighted

In Section H of the **Supporting Documentation**, you must address seven areas regarding confidentiality and protection of human subjects. If any or all of the seven areas are not relevant to your project, you must document why. No points will be assigned to this section.

This information will:

- c Reveal if the protection of human subjects is adequate or if more protection is needed according to standards set forth in 45 CFR 46.

- c Be considered when making funding decisions.

Note: Part II of the GFA provides additional information regarding confidentiality and the requirements of 45 CFR 46, Protection of Human Subjects, including filing an Assurance of Compliance and documentation of Institutional Review Board (IRB) approvals.

Some projects may expose people to risks in many different ways. In this section of your application, you will need to:

- c Report any possible risks for people in your project.
- c State how you plan to protect them from those risks.
- c Discuss how each type of risk will be dealt with, or why it does not apply to the project.

The following seven areas **must be discussed**:

Ø Protect Clients and Staff from Potential Risks

- c Identify and describe any foreseeable physical, medical, psychological, social, legal, or other risks or adverse affects.
- c Discuss risks which are due either to participation in the project itself, or to the evaluation activities.
- c Describe the procedures that will be followed to minimize or protect

participants against potential risks, including risks to confidentiality.

- c Give plans to provide help if there are adverse effects to participants.

- c Where appropriate, describe alternative treatments and procedures that may be beneficial to the subjects. If you do not decide to use these other beneficial treatments, provide the reasons for not using them.

Ü Fair Selection of Participants

- c Describe the target population(s) for the proposed project. Include racial/ethnic background, gender, age, sexual orientation, disability and literacy levels. Address other important factors such as homeless youth, foster children, children of substance abusers, pregnant women, or other special population groups.

- c Explain the reasons for using special types of participants, such as pregnant women, children, people with mental disabilities, people in institutions, prisoners, or others who are likely to be vulnerable to HIV/AIDS.

- c Explain the reasons for **including or excluding** participants.

- c Explain how you will recruit and select participants. Identify who will select participants.

Ü Absence of Coercion

- c Explain if participation in the project is voluntary or required. Identify possible reasons why it is required. For example, court orders requiring people to participate in a program.

- c If you plan to pay participants, state how participants will be awarded money or gifts.

- c State how volunteer participants will be told that they may receive services and incentives even if they do not complete the study.

Ü Data Collection

- c Identify from whom you will collect data, for example, participants themselves, family members, teachers, others. Explain how you will collect data and list the site. For example, will you use school records, interviews, psychological assessments, observation, questionnaires, or other sources?

- c Identify what type of specimens (e.g., urine, blood) will be used, if any. State if the material will be used just for evaluation and research or if other use will be made. Also, if needed, describe how the material will be monitored to ensure the safety of participants.

Ü Privacy and Confidentiality

- c List how you will ensure privacy and confidentiality. Include who will collect data and how it will be collected. Describe:

- how you will use data collection instruments;

- where data will be stored;

- who will or will not have access to information; and

- how the identity of participants will be kept private. For example, through the use of a coding system on data records, limiting access to records, or storing identifiers separately from data.

Note: If applicable, grantees must agree to maintain the confidentiality of alcohol and drug abuse client records according to the provisions of Title 42 of the Code of Federal Regulations, Part 2 (42 CFR, Part 2).

Y Adequate Consent Procedures

c List what information will be given to participants regarding the nature and purpose of their participation. Include how the data will be used and how you will keep the data private. Also, include:

- if their participation is voluntary,

- their right to leave the project at any time without problems,

- risks from the project, and

- plans to protect clients from these risks.

c Explain how you will get consent for youth, the elderly, people with limited

reading skills, and people who do not use English as their first language.

Note: If the project poses potential physical, medical, psychological, legal, social or other risks, you should get **written** informed consent.

c Indicate if you will get informed consent from participants or from their parents or legal guardians. Describe how the consent will be documented. For example:

- Will you read the consent forms?

- Will you ask prospective participants questions to be sure they understand the forms?

- Will you give them copies of what they sign?

Note: Never imply that the participant waives or appears to waive any legal rights, may not end involvement with the project, or releases your project or its agents from liability for negligence.

c Describe if separate consents will be obtained for different stages or parts of the project. For example:

- Will they be needed for both the treatment intervention and for the collection of data?

- Will individuals who do not consent to having individually identifiable data collected for evaluation purposes be allowed to participate in the project?

► Risk/Benefit Discussion

Discuss why the risks are reasonable compared to expected benefits and importance of the knowledge from the project.

Special Considerations and Requirements

SAMHSA's policies and special considerations and requirements can be found in **Part II of the GFA** in the sections by the same names. The policies, special considerations, and requirements related to this program are:

- c Population Inclusion Requirement,
- c Government Performance Monitoring,
- c Health People 2010: The Healthy People 2010 focus areas related to this program are in Chapter 26: Substance Abuse,
- c Consumer Bill of Rights,
- c Promoting Non-use of Tobacco,
- c Letter of Intent,
- c Intergovernmental Review (E.O. 12372), and
- c Confidentiality/Protection of Human Subjects.

NATIONAL TREATMENT PLAN (NTP)

The Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Treatment (CSAT) initiated *Changing the Conversation: Improving Substance Abuse Treatment: The National Treatment Plan Initiative* (NTP) to build on recent advances in the field, to bring together the best ideas about improving treatment, and to identify action recommendations that could translate ideas into practice.

The NTP combines the recommendations of five Expert Panels, with input from six public hearings and solicitation of experience and ideas through written and online comments, into a five-point strategy: (1) Invest for Results; (2) No Wrong Door to Treatment; (3) Commit to Quality; (4) Change Attitudes; and (5) Build Partnerships. The recommendations represent the collective vision of the participants in the NTP conversation. The goal of these recommendations is to ensure that an individual needing treatment, regardless of the door or system through which he or she enters, will be identified and assessed and will receive treatment either directly or through appropriate referral. Systems must make every door the right door.

The NTP is a document for the entire substance abuse treatment field, not just CSAT. Implementing the NTP's recommendations go beyond CSAT or the Federal Government and will require commitments of energy and resources by a broad range of partners including State and local governments, providers, persons in recovery, foundations, researchers, the academic community, etc.

Copies of the NTP may be downloaded from the SAMHSA web site, www.samhsa.gov (click on CSAT and then on NTP), or from the National Clearinghouse for Alcohol and Drug Information (NCADI) at 1-800-729-6686.

CORE PROTOCOL DESCRIPTIONS**! ADMINISTRATIVE, CLIENT-LEVEL TREATMENT DATA**

The Administrative, Client-Level Treatment Data Core Protocol will be used by all States receiving an award under the STNAP. Administrative client-level data provides States with valuable data for meeting legislative requirements for annual reporting of core data and can also be used to address other pertinent issues as described in Part I of the GFA. This core protocol involves State treatment admissions and potentially encounter and discharge data. This activity extends basic treatment episodes data in order to expand the analysis of treatment utilization patterns. The core requirement is to collect a unique person identifier in addition to admission data, currently reported to SAMHSA, and to demonstrate that identifiers can be used to match and link service records for the same person over time and among providers. In addition, States are encouraged to expand their data set to include information such as case severity (at discharge, as well as at admission), socio-economic status, costs/risks to society (e.g., criminal activity), treatment services delivered, and treatment costs.

! STNAP SURVEY

States are required to generate general population sub-State estimates for substance abuse in their SAPT Block Grant application. In addition, data are needed at the sub-State level for planning resource allocation for both prevention and treatment programs. The core protocol is to be used for addressing the need to generate sub-State prevalence estimates and is a primary data collection activity that can be administered by telephone to household members or special populations.

The STNAP Survey core protocol requires States to collect a standard minimum data set using the STNAP Survey. The survey includes questions about basic demographics, substance use and dependence and abuse based on DSM-IV criteria. States are not limited to the questions on the survey and may want to add questions, for instance, on drugs not included or modules on topics such as mental or physical health.

! CRIMINAL JUSTICE

Determining the prevalence of drug use among arrestees has been generally recognized as one approach for studying the epidemiology of certain illicit drug use in communities. These studies capture a special population with a high risk of drug use and abuse, particularly abuse of drugs with low prevalence in the general population, such as cocaine, heroin, and methamphetamine. The criminal justice protocol is comprised of two separate but related protocols to collect information from either arrestees or inmates. The arrestee protocol, called the ADAM-CSAT Core Protocol, requires the applicant to agree to collect arrestee data in collaboration with the National Institute of Justice through its Arrestee Drug Abuse Monitoring (ADAM) Program. A three-page set of additional questions of interest to CSAT is required. Applicants may choose any or all of the following three options.

1. Negotiate an ADAM-CSAT Partner site and follow the ADAM protocol
2. Add an addendum to an already existing site, (e.g., HIV, domestic violence) to be administered twice a year
3. Add an outreach component (e.g., rural areas, American Indian Reservations, other hard-to-reach populations) to be administered periodically

The Inmate Population Protocol is structured to gather information from inmates who abused drugs before entering jail or prison and their need for drug abuse treatment. The study population represents a randomly selected group of incoming inmates. The core questionnaire is modeled on the ADAM survey, at least in certain key questions that will allow comparisons at the question-level between surveys. Applicants have a choice to use either the Inmate questionnaire or the STNAP Survey questionnaire. Applicants may add questions to address specific local needs.

! DATABASE LINKAGES

This core protocol supports efforts to identify and link one or more existing administrative data sets routinely collected by government agencies to State client level treatment episode data by means of a unique person identifier. The treatment episode data must be linked to one of the following three core data sets.

1. Hospital discharge abstracts using UB_92, HCFA-1500, or other standardized format and/or Medicaid data sets
2. Criminal justice data obtained from State arrest data, using Category A and B crimes as defined in the UCR where possible, for comparability across States
3. Mortality data derived from death certificates

Applicants are not limited to the core protocol data set requirements. Enhancements that could be used may include:

- additional data sets in the areas of health care, criminal justice, mortality or new areas, e.g., socio-economic or adolescents;
- additional variables to required core data sets and/or any enhancements used in the linking process; and
- conducting additional, and possibly more complex analyses.

This core protocol establishes a process for using unique person identifiers that will maximize true matches. The resulting linked database system allows for States to create ongoing information systems at the client level. These information systems can provide information for prevalence estimates, and process and outcome evaluations of the effects of treatment at the

client level that can be used to support policy decisions aimed at increasing treatment effectiveness.

c **SOCIAL INDICATORS**

CSAT views the use of social indicator data as an opportunity for States to use existing data for creating ongoing information systems. The social indicator core protocol relies primarily on secondary analysis of existing archival or administrative data collected by government agencies. The primary focus is on aggregate data at the county and State levels. This core protocol requires utilization of data from four core data sets: population (Census data), mortality (State reported data to the National Center for Health Statistics), criminal justice (Uniform Crime data), and substance abuse treatment admissions data (State reported treatment episode data). States may propose using additional data sources for supplemental studies. The core protocol suggests that supplemental studies be conducted to address the gaps in the core data sets, as well as using additional data sets (e.g., additional census variables, additional criminal justice data) and analyses.

For copies of core protocols, please call Nita Fleagle, GPO, on (301)-443-8572 or e-mail at >nfleagle@samhsa.gov<.